

REMARKS

The only issue outstanding in the office action of December 28, 2009, is the rejection under 35 U.S.C. 112. The Examiner is thanked for indicating withdrawal of the previous rejections under 35 U.S.C. 102 and 103. Thus, the only issue for consideration herein is whether the added language to claim 10 represents new matter. The Examiner is thanked for following proper procedure as set forth in MPEP §2163, concerning entry of the amendment.

In order to expedite prosecution, claim 10 has again been amended in order to recite the exact language contained in paragraph 24 of the specification, “decellularized even in deep interior portions.” It is submitted that this language does not change the scope of the claim, as much as it represents “complete” decellurization as previously recited. Decellularization even in deep interior portions is not disclosed or suggested by Login, previously employed in the rejections. As will be recalled, Login discloses a process employing microwave irradiation along with a physiologic salt solution or a dilute aldehyde solution, to preserve tissue in the preparation of bioprosthesis for implantation into patient. In the method of Login et al., a specimen of biological tissue is immersed in an osmotically balanced solution (OBS). The purpose of utilizing OBS is to *prevent the loss* of important cellular constituents due to diffusion. See, col. 5, lines 9-11. This is consistent with “tissue fixing” e. g. by exposure to glutaraldehyde or formaldehyde, note the discussion of cell fixing at column 2, along 31-33 and lines 52-53 patent. Such “fixing” is *not* decellularization in the deep interior of the tissue, i.e., in a complete matter so as remove all cells. Treatment or immersion a solution such as osmotically balanced solution does not enable removal of cellular components, even with the microwave radiation treatment of the patent. In Login’s method, the tissue immersed in OBS initially at room temperature (approximately 20°C) is irradiated with microwave energy at a sufficient does and for a sufficient time such that the temperature of the solution is within the range of 35°C to 50°C. This time is short, e.g. between one and fifty seconds. See, e.g. claim 6. Thus, Login does not disclose a process which can result in deep interior decellularization.

In the present invention, the tissue immersed in the treating solution is irradiated with considerably greater intensity, e.g., with microwaves at a frequency of 2450MHz (the frequency

of a standard microwave oven) for a net period of time so as to achieve complete decellularization or for at least 1 hour while maintaining the temperature in the range of 0°C to 40°C, (see Claim 10). The duration of microwave irradiation in Claim 10 is at least 72 times greater than the duration of microwave irradiation of Login's method. Moreover, in Login, the microwave oven will be automatically shut off when the pre-set final irradiation temperature of the solution is obtained (col. 4, lines 65-67). In other words, Login never irradiates the tissue specimen in OBS with microwave energy at a dose and for a length of time such that temperature of the solution reaches above patentees' preset temperature of 35°C to 50°C. Such duration of microwave irradiation is not sufficient to achieve deep interior decellularization. With a large enough dose of microwave energy to remove cellular membrane and release intracellular components, such as in the present invention, it is necessary to cool the tissue in the treating solution to maintain the generating temperature from 0°C to 40°C as recited in the claims.

In addition, the disclosure of Login is simply does not suggest to one of ordinary skill, particularly in the absence of a decellularizing chemical, complete decellularization and/or the conditions recited in the present invention. The osmotically balanced solutions (OBS) of Login et al. are free of any decellularizing chemical such as the presently recited detergents and, therefore, are not capable of decellularizing native biological tissues.

Prior Office Actions have cited the disclosures of Giberson and Boon to attempt to remedy the deficiencies of the primary reference. However, these secondary references fail to do so. In Giberson a tissue specimen is immersed in a formalin based solution, and irradiated with microwaves. Formalin is well known as a fixation chemical of biological tissues for microscopic inspection. Since the morphological characteristics of the tissue specimen must be preserved for diagnostic purposes, Giberson does not remove any cellular component from the tissue. Boon teaches the use of alcohol or glutaraldehyde as an immersion fluid (page 7, lines 51-55) when irradiating tissue with microwaves. Thus, again, only fixation is taught, and not complete decellularization. These secondary references accordingly do nothing to remedy the deficiencies of Login, and even in combination do not suggest the present claims.

Accordingly, it is submitted that no rejection under 35 U.S.C. 102 or 103 should be made herein, and that the claims of the application are in condition for allowance. Passage to issue is accordingly respectfully requested. However, should the Examiner have any questions or

comments, he or she is cordially invited to telephone the undersigned at the number below.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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